K122270

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## Section 5. 510(k) Summary for OverTube™ Endoscopic Access System

SEP 28 2012

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|---|---|
| Company: | Apollo Endosurgery, Inc.<br>7000 Bee Cave Road, Suite 350<br>Austin, TX, USA 78746 |
| Contact Person: | Heather Crawford, RAC<br>Director of Quality and Regulatory<br>Email: heather.crawford@apolloendo.com<br>Office phone: 512.328.9990 extension 244<br>Fax: 512.328.9994 |
| Date Prepared: | 18 September 2012 |
| Device: | Trade Name: OverTube™ Endoscopic Access System<br>Regulation Number: 21 CFR § 876.1500<br>Regulation Description: Endoscope and accessories<br>Product Code: FED<br>Classification Panel: Gastroenterology/Urology<br>Device Classification: Class II |
| Predicate Device(s): | 1. K040836: US Endoscopy Disposable Overtube |
| Indications for Use: | To be used in conjunction with an endoscope for foreign body removal or endoscopic procedures requiring multiple insertions of the endoscope into the lower or upper gastrointestinal tract. |
| Device Description: | The OverTube™ Endoscopic Access System is comprised of a single, polymer extrusion shaft reinforced with a metallic coil. The hub located at the proximal end of the device contains a cuff seal which can be inflated with air using a syringe to reduce loss of pressure when insufflation is used. The device is available in a single effective length of 27 cm with a tapered distal tip. The OverTube™ Endoscopic Access System will be delivered in a manner that a clinician may open one (1) OverTube per clinical procedure. The OverTube™ Endoscopic Access System will be provided in both sterile and non-sterile models. The sterile model is terminally sterilized by ethylene oxide (EO). |

**Technological Characteristics and Substantial Equivalence**

The following table compares the OverTube™ Endoscopic Access System to the predicate device with respect to intended use and technological characteristics, providing more detailed information regarding the basis for the determination of substantial equivalence.

**Table 5-1. Device Comparison Table**

| Parameter | Apollo Endosurgery OverTube™ Endoscopic Access System | US Endoscopy Disposable Overtube (Guardus®) |
|---|---|---|
| 510(k) Number | To be assigned | K040836 |
| Indications for Use | To be used in conjunction with an endoscope for foreign body removal or endoscopic procedures requiring multiple insertions of the endoscope into the lower or upper gastrointestinal tract. | The disposable Overtube is a device used in conjunction with a flexible endoscope for foreign body or tissue retrieval and/or for endoscopic procedures requiring multiple endoscope intubations. |
| Regulation Number | 876.1500 | 876.1500 |
| FDA Product Code | FED | KOG |
| Prescription / OTC Use | Prescription | Prescription |
| Single-Use / Reusable | Single-Use | Single-Use |
| ***Dimensions*** | | |
| Effective Length | 27 cm | 25 cm – 50 cm |
| Overtube Shaft OD | 19.5 mm | 19.5 mm |
| Overtube Shaft ID | 16.7 mm | 16.7 mm |
| Tapered Tip ID | 11 mm | 10.4 mm (insertion tube)<br>16.8 mm (outer tube) |
| ***Physical Characteristics*** | | |
| Overall Design | Single tube | Dual tube |
| Compatible Scope OD (mm) | 10 mm – 16 mm | 8.6 mm – 11.7 mm |
| Reinforcement Material | Wire coil design | Wire coil design |
| Tapered Tip | Yes | Yes |
| Insufflation Method | Cuff | Cap |
| ***Sterilization and Shelf Life*** | | |
| Sterility | Sterile and Non-sterile | Non-sterile only |
| Sterilization Method | Ethylene oxide | None |
| Primary Package | Pouch | Tray |
| Shelf Life (Use By Date) | Three (3) years | Three (3) years |
| Units per Shelf Box | Three (3) | Three (3) |

**Summary of Non-Clinical Data Submitted**

Performance testing was conducted on the OverTube™ Endoscopic Access System to establish substantial equivalence. Functional performance testing included insertion and removal force requirements, shaft deflection, leakage rate, bond strength and foreign body removal. The OverTube™ Endoscopic Access System was subjected to biocompatibility evaluation in accordance with ISO 10993-1:2009. Additionally the OverTube™ Endoscopic Access System was adopted into the existing ethylene oxide sterilization cycle which was validated in accordance with ISO 11135-1:2007.

**Safety and Effectiveness**

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the OverTube™ Endoscopic Access System and predicate device do not raise any questions regarding its safety and effectiveness. The OverTube™ Endoscopic Access System, as designed and manufactured, therefore is determined to be substantially equivalent to the referenced predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Heather Crawford, RAC
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SEP 2 8 2012

Re: K122270
Trade/Device Name: OverTube™ Endoscopic Access System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: July 27, 2012
Received: July 30, 2012

Dear Ms. Crawford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K122270

Device Name: OverTube™ Endoscopic Access System

Indications for Use: To be used in conjunction with an endoscope for foreign body removal or endoscopic procedures requiring multiple insertions of the endoscope into the lower or upper gastrointestinal tract.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122270